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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,970	01/13/2004	Kevin T. Foley	MSDI-223/PC-444.06	3770
52196 7590 12/26/2008 KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709				
EXAMINER HOFFMAN, MARY C				
ART UNIT		PAPER NUMBER		
3733				
MAIL DATE		DELIVERY MODE		
12/26/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/756,970

**Applicant(s)**

FOLEY ET AL.

**Examiner**

MARY HOFFMAN

**Art Unit**

3733

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 55-63, 65-74 and 94-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-63, 65-70, 74 and 94-103 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/13/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the embodiment with only one transverse projection must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 66-67, 69 and 94-103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims (66, 69 and 94) recite at least one but no more than two transverse projection. The claims also recite a pair of longitudinally extending slots. The disclosure does not show one transverse projections with two slots.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55-63, 65-70, 74 and 94-103 rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. (US 5,522,790).

Moll et al. disclose the claimed invention (see FIGS 12F-12G) including an elongate member extending along a longitudinal axis and including a deformable distal

portion having an initial configuration for placement adjacent a spinal structure and an expanded configuration wherein the deformable distal portion is outwardly deformed to define transverse projections, each of the transverse projections arranged along a single transverse axis, and wherein formation of the transverse projections is directionally controlled such that each of the transverse projections extends in a uniaxial direction aligned with the single transverse axis such that at least a portion of the spinal structure is uniaxially displaced along the transverse axis; and wherein the elongate member comprises an inner actuator member disposed within an outer sleeve member, a distal portion of the sleeve member being outwardly deformed to define the transverse projections in response to relative displacement between the actuator member and the sleeve member; and wherein the deformable distal portion comprises at least one flexible strip of material having a length extending along the longitudinal axis, the flexible strip of material having an outwardly buckled configuration defining the at least one transverse projection, the flexible strip of material configured such that the relative displacement between the actuator member and the sleeve member transitions the flexible strip of material to the outwardly buckled configuration and provides the transverse projection with an arc-shaped outer curvature extending along the length of the flexible strip of material and configured to bear against vertebral bone. The displacement of the at least a portion of the spinal structure is directionally controlled. The displacement of the at least a portion of the spinal structure is unidirectional. The outward deformation of the transverse projections is selectively controlled to generate a controlled magnitude of force against the at least a portion of the spinal structure. The

expanded configuration defines a single pair of transverse projections arranged generally opposite one another along the single transverse axis. The relative displacement between the actuator member and the sleeve member is relative linear displacement. The relative displacement between the actuator member and the sleeve member is regulated to generate a controlled magnitude of force against the at least a portion of the spinal structure. The instrumentation further comprising an actuator mechanism coupled between the actuator member and the sleeve member and being operable to impart the relative displacement therebetween. The actuator mechanism comprises a first portion coupled to the actuator member; and a second portion coupled to the sleeve member and engaged with the first portion; and wherein relative rotation between the first and second portions imparts relative linear displacement between the actuator member and the sleeve member to cause the distal portion of the sleeve member to reform from the initial configuration toward the expanded configuration. The deformable distal portion comprises a pair of the flexible strips of material disposed generally opposite one another, the pair of flexible strips of material defining a pair of transverse projections disposed generally opposite one another when transitioned to the outwardly buckled configuration. The predetermined shape including a series of arcuate portions. The deformable distal portion defines a plurality of slots, the slots facilitating outward buckling of the deformable distal portion to define the transverse projections. The predetermined shape is at least partially comprised of an hour-glass shape. The deformable distal portion is at least partially formed of a shape-memory material, the deformable distal portion being reformed from the initial configuration toward the

expanded configuration in response to the imposition of stress and automatically reformed back toward the initial configuration upon removal of the stress.

Moll et al. do not explicitly teach two oppositely spaced transverse projections. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the Moll et al. device with two, oppositely spaced projections, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Furthermore, it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Examiner, Art Unit 3733  
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